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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,500	03/18/2005	Silvia Berlanga de Moraes Barros	ABARR.0101	4409
22858	7590	10/06/2010		
CARSTENS & CAHOON, LLP 13760 NOEL ROAD, SUITE 900 DALLAS, TX 75240			EXAMINER TATE, CHRISTOPHER ROBIN	
			ART UNIT	PAPER NUMBER
			1655	
			MAIL DATE	DELIVERY MODE
			10/06/2010	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte SILVIA BERLANGA DE MORAES BARROS
and CRISTINA DISLICH ROPKE

Appeal 2010-006399
Application 10/528,500
Technology Center 1600

Before DONALD E. ADAMS, JEFFREY N. FREDMAN, and
STEPHEN WALSH, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL¹

This is an appeal under 35 U.S.C. § 134 involving claims to a gel composition. The Examiner rejected the claims as lacking descriptive support and as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the “MAIL DATE” (paper delivery mode) or the “NOTIFICATION DATE” (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

Statement of the Case

The Claims

Claims 24, 27, and 28 are on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claims 24 is representative and reads as follows:

24. A gel composition comprising:
a) carboxymethylcellulose from 0.01 to 2.0%;
b) propylene glycol from 5.0 to 20.0%;
c) methylparaben from 0.1 to 1.0%; and
d) 4-nerolidylcatechol from 0.005 to 20.0%.

The issues

- A. The Examiner rejected claims 24, 27, and 28 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement (Ans. 4).
- B. The Examiner rejected claims 24, 27, and 28 under 35 U.S.C. § 103(a) as obvious over Ropke (2002),² Ropke (2000),³ and Wheeler⁴ (Ans. 5-6).

² Ropke et al., *Topical Applicati[o]n of Pothomorphe umbellata root extract prevents a-tocopherol from depletion after UV-irradiation on hairless mouse skin*, 33 FREE RADICAL BIOL. MED. Abstract #527 (July 2002).

³ Ropke et al., *Evaluation of the antioxidant activity of Pothmorphe umbellata L. MIQ on the skin*, ANNALS OF THE 14TH NAT'L COSMETOLOGY CONGRESS OF THE BRAZILIAN COSMETOLOGY ASS'N 483-500 (2000) (renumbered pages 1-23 in translation).

⁴ Derek Wheeler, US 6,165,479, issued Dec. 26, 2000.

C. The Examiner rejected claims 24, 27, and 28 under 35 U.S.C. § 103(a) as obvious over Uchiyama,⁵ Barros,⁶ Desmarchelier,⁷ and Wheeler (Ans. 7-9).

A. 35 U.S.C. § 112, first paragraph, written description

The Examiner finds that “[c]laims 24 and 28 recite various numerical range limitations regarding the amounts of elements a) through c) which are not supported by the instant specification (i.e., the Examiner could not find support for the narrower ranges instantly claimed, nor did Applicants particular[ly] point to such support within the instant specification)” (Ans. 4).

Appellants contend that “[r]anges in a claim can be narrower than those disclosed in [the] specification” (App. Br. 4). Appellants contend that the “claimed ranges are within the ranges disclosed in the specification, like the range in *In re Wertheim*” (App. Br. 5).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that the numerical range limitations lack descriptive support in the Specification?

⁵ Uchiyama et al., JP 2001-122763, published May 8, 2001 (renumbered pages 1-24 in translation).

⁶ Barros et al., *Antioxidant activity of ethanolic extracts of Pothomorphe umbellata L. Miq. (Pariparoba)*, 48 CIENCIA E CULTURA J. BRAZILIAN ASS’N ADVANCEMENT SCIENCE 114-116 (1996).

⁷ Desmarchelier et al., *4-Nerolidylcatechol from Pothomorphe Spp. Scavenges peroxy radicals and inhibits Fe(II)-dependent DNA damage*, 63 PLANTA MED. 561-563 (1997).

Findings of Fact

1. Claim 24 recites ranges of 0.01 to 2.0% for carboxymethylcellulose, 5.0 to 20.0 % for propylene glycol, and 0.1 to 1.0% for methylparaben (*see* Claim 24).

2. The Specification teaches that a proposed composition is comprised of:
- a) carboxymethylcellulose 0.01 – 10.0%
 - b) propyleneglycol 0.001 – 50.0%
 - c) methylparaben 0.001 – 3.0 %
 - d) *Pothomorphe umbellata* standardized extract, so that the formulation contains 0.005 to 20.0% of 4-nerolidylcatechol
 - e) distilled water q.s.p. 100.0%.

(Spec. 11, ll. 6-13).

Principles of Law

The original disclosure of a broader range may support the recitation of a narrower range, even though the narrower range had not been explicitly disclosed. *In re Wertheim*, 541 F.2d 257, 262-63 (CCPA 1976). However, as noted in *Wertheim*, determination of questions relating to the written description requirement depend upon the facts of each particular case (*id.*).

Analysis

There is no dispute that the disclosure in the original specification is to a series of ranges which encompass the values currently found in Claim 24 (FF 1-2). The issue is whether Appellants had possession of the narrower ranges based upon this disclosure. We note that a range is a shorthand format for presenting information, where the range is understood to

encompass each discrete point. For example, the range of 3-nerolidylcatechol found in Claim 24 is 0.005 to 20.0%. This ordinary artisan would recognize that this range encompasses points such as 0.1 %, 1%, 3%, 5%, or 10%. Appellants' ranges in Claim 24 are equivalent to the unwieldy and lengthy description of every possible combination of these discrete values, presented in an easily understood shorthand format using ranges.

In Appellants' response of November 3, 2008, Appellants amended the claims to result in "specific ranges not disclosed by any of the cited prior art" (App. Response 11/03/08, pg. 7). The ranges were amended in an attempt to differentiate the prior art, which amendment the Examiner identifies as failing to satisfy the written description requirement. *See Engineering Development Laboratories v. Radio Corp. of America*, 153 F.2d 523, 526 (2nd Cir. 1946) ("The addition of a new element in a combination, while all the rest remain, releases a part of the disclosure to the public demesne, and to that there can obviously be no objection. Applicants ordinarily begin with as broad claims as they can hope to sustain; and they retreat progressively as the examiner forces them by the prior art he turns up in the Office. No other course is really open to them").

Conclusion of Law

The evidence of record does not support the Examiner's conclusion that the numerical range limitations lack descriptive support in the Specification.

B. 35 U.S.C. § 103(a) over *Ropke* (2002), *Ropke* (2000), and *Wheeler*

The Examiner finds it would have been obvious to incorporate the *Pothomorphe umbellata* extract preparation having strong therapeutic antioxidant activity as

taught by each of the Ropke et al. references into a conventional skin therapeutic formulation (e.g., as an effective antioxidant) - including a skin gel, containing the commonly-employed skin care ingredients carboxymethylcellulose, propylene glycol, and methylparaben therein based upon the beneficial teachings provided by Wheeler.

(Ans. 6).

Appellants contend that “although the antioxidant activity of *Pariparoba* was known, it is not obvious to imagine which specific gel formulation serves as a vehicle for this drug in order to obtain a therapeutically effective gel composition” (App. Br. 7). Appellants contend that “it was not obvious at time of claimed invention as to which specific formulation containing an extract of *Pothomorphe umbellata* and/or 4-nerolidylcatechol would be photostable.” (App. Br. 8).

Appellants contend that:

the Ropke et al. (2002) reference should not be considered prior art by the Examiner, since it was published by the inventors within the grace period of the present application (Ropke et al. (2002) was published by the inventors themselves, two months prior to the filing of the Brazilian priority application (PI0204130-8) which was filed on September 18th, 2002).

(App. Br. 9). Appellants contend that “the Ropke et al. (2000) reference does not disclose a gel” (App. Br. 9).

Appellants contend that “the present invention is not based on antioxidant activity, but on photoprotective activity (photodamage). It is not possible to say that any substance that presents antioxidant activity is a

photoprotector. Therefore, it would not be obvious to one of ordinary skill in the art to deduce this property” (App. Br. 10).

The issues with respect to this rejection are:

- (i) Is the Ropke (2002) reference prior art to the instant claims?
- (ii) Does the evidence of record support the Examiner’s conclusion that the claimed invention is obvious over the prior art?

Findings of Fact

3. There is no dispute that Ropke (2002) was published in July 2002 (*see* Ans. 3).

4. There is no dispute that instant application 10/528,500 claims priority to Brazilian application PI0204130-8, which was filed September 18, 2002, which was subsequently filed as an international application on September 17, 2003. The application was filed in the United States on March 18, 2005.

5. Ropke (2002) teaches “we evaluated the influence of topical application of *P. umbellata* root extract gel, containing 0,1% of 4-nerolidylcatechol, on the antioxidant network in ultraviolet-induced oxidative damage in Hairless mouse skin” (Ropke (2002) abstract).

6. Ropke (2002) teaches that “4-nerolidylcatechol was absorbed in biological conditions and was stable when exposed to UV-irradiation . . . topical *P. umbellata* treatment protected α -tocopherol from depletion after UV-irradiation” (Ropke (2002) abstract).

7. Ropke (2002) teaches that “[t]hese data demonstrate that *P. umbellata* may successfully [be] employed as a topical photoprotective agent” (Ropke (2002) abstract).

8. Ropke (2000) teaches that the “antioxidant activity of Pothomorphe umbellata was assessed using ‘in vitro’ test tubes and indicated a major lipoperoxidation inhibiting effect of a hydroalcoholic extract of the root resulting from the presence of 4-nerolidylcatechol” (Ropke (2000) 4).

9. Ropke (2000) teaches that the “powerful antioxidant activity of the Pothomorphe umbellata root extract suggests it[s] use as an active principle in cosmetic formulations which have the objective of combating the damaging effects of free radicals” (Ropke (2000) 18).

10. Wheeler teaches “a stable dispersion comprising an oil-based biliquid foam an[d] an aqueous gel which may be a colloidal aqueous gel” (Wheeler, col. 2, ll. 35-37).

11. Wheeler teaches that the “aqueous phase will in general comprise a colloidal polymer or gum . . . Suitable polymers or gums are, for example, . . . carboxymethylcellulose” (Wheeler, col. 2, ll. 58-65).

12. Wheeler teaches, in Example 1, a skin cleansing product where the “preservatives (methylparaben and imidazolidinylurea) were dissolved in the propylene glycol” which resulted in “a clear aqueous gel” (Wheeler, col. 4, ll. 60-67).

13. Wheeler teaches the use of 0.08 % methylparaben and 3% propylene glycol in Example 1 (*see* Wheeler, col. 4, ll. 52-56).

14. Wheeler teaches that the formulation “may still further contain an antioxidant” (Wheeler, col. 3, l. 53).

Principles of Law

35 U.S.C. § 102(b) states that a person shall be entitled to a patent unless “the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the *date of the application for patent in the United States*”(emphasis added).

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007). “If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability.” *Id.* at 417. Moreover, an “[e]xpress suggestion to substitute one equivalent for another need not be present to render such substitution obvious.” *In re Fout*, 675 F.2d 297, 301 (CCPA 1982). As noted by the Court in *KSR*, “[a] person of ordinary skill is also a person of ordinary creativity, not an automaton.” *KSR* at 421.

Analysis

We begin by addressing the question of whether Ropke (2002) is properly cited as prior art. Appellants contend that:

the Ropke et al. (2002) reference should not be considered prior art by the Examiner, since it was published by the inventors within the grace period of the present application (Ropke et al. (2002) was published by the inventors themselves, two months prior to the filing of the Brazilian priority application (PI0204130-8) which was filed on September 18th, 2002).

(App. Br. 9). However, the statute in § 102(b) places a statutory bar under which prior art published more than one year prior to the date of application

in the United States cannot be overcome. Since the Brazilian filing date was not an application for patent in the United States, Ropke (2002) was published more than one year before the earliest filing date of application in the United States. Therefore, consonant with § 102(b), Ropke (2002) is prior art to the instant claims.

Ropke (2002) teaches “topical application of *P. umbellata* root extract gel, containing 0,1% of 4-nerolidylcatechol, on the antioxidant network in ultraviolet-induced oxidative damage in Hairless mouse skin” (Ropke (2002) abstract; FF 5). Ropke (2000) teaches that the “powerful antioxidant activity of the Pothomorphe umbellata root extract suggests it[s] use as an active principle in cosmetic formulations which have the objective of combating the damaging effects of free radicals” (Ropke (2000) 18; FF 9).

Wheeler teaches skin cleansing products with antioxidants, carboxymethylcellulose, where the “preservatives (methylparaben and imidazolidinylurea) were dissolved in the propylene glycol” which resulted in “a clear aqueous gel” (Wheeler, col. 4, ll. 60-67; FF 12). Wheeler teaches the use of 0.08 % methylparaben and 3% propylene glycol in Example 1 (see Wheeler, col. 4, ll. 52-56; FF 13).

We agree with the Examiner that it would have been obvious to the ordinary artisan to incorporate the active antioxidant 4-nerolidylcatechol from *P. umbellata* root extract taught by Ropke (2002) and Ropke (2000) with the skin gel components taught by Wheeler to obtain a skin gel which incorporates the “powerful antioxidant activity of the Pothomorphe umbellata root extract” (Ropke (2000) 18; FF 9).

Appellants contend that “it was not obvious at time of claimed invention as to which specific formulation containing an extract of *Pothomorphe umbellata* and/or 4-nerolidylcatechol would be photostable.” (App. Br. 8).

We are not persuaded. Ropke (2002) teaches that “4-nerolidylcatechol was absorbed in biological conditions and was stable when exposed to UV-irradiation . . . topical *P. umbellata* treatment protected α -tocopherol from depletion after UV-irradiation” (Ropke (2002) abstract; FF 6). Appellants have provided no evidence to rebut this teaching of Ropke (2002) and demonstrate any unpredictability in the use of 4-nerolidylcatechol.

We also conclude that the close, but not overlapping, range of amounts of components disclosed by Wheeler would reasonably be obtained by those in the art seeking to optimize the properties of the composition. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“[A] *prima facie* case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties.”). Further, to the extent that Appellants are contending that the formulation of Wheeler differs from that claimed, Appellants have provided not rebutted the presumption that a composition with 0.08 % methylparaben and 3% propylene glycol of Wheeler, for example (FF 3), would not have been expected to have the substantially the same properties as the claimed composition with 0.1 % methylparaben and 5% propylene glycol (*see* Claim 24).

Appellants contend that “the Ropke et al. (2000) reference does not disclose a gel” (App. Br. 9). Appellants contend that “the present invention is not based on antioxidant activity, but on photoprotective activity (photodamage). It is not possible to say that any substance that presents antioxidant activity is a photoprotector. Therefore, it would not be obvious to one of ordinary skill in the art to deduce this property” (App. Br. 10).

We are not persuaded. Ropke (2002) teaches “we evaluated the influence of topical application of *P. umbellata* root extract gel, containing 0,1% of 4-nerolidylcatechol, on the antioxidant network in ultraviolet-induced oxidative damage in Hairless mouse skin” (Ropke (2002) abstract; FF 5). Thus Ropke (2002) expressly teaches a gel and expressly teaches evaluating resistance to ultraviolet-induced oxidative damage, which is photoprotective activity (FF 5-6).

Conclusion of Law

- (i) The Ropke (2002) reference is prior art to the instant claims.
- (ii) The evidence of record supports the Examiner’s conclusion that the claimed invention is obvious over the prior art.

C. 35 U.S.C. § 103(a) over Uchiyama, Barros, Desmarchelier, and Wheeler

The Examiner finds that it would have been obvious to incorporate an alcoholic (e.g., ethanolic or methanolic) extract of *Pothomorphe umbellata* within the skin therapeutic composition (having antioxidant activity) as taught by Uchiyama et al, especially since Uchiyama et al. beneficially teaches that ethanolic and methanolic solvents are effective solvents to employ, and Barros et al. and Desmarchelier et al. beneficially teaches that such

alcoholic solvents provide a *Pothomorphe umbellata* extract having strong antioxidant activity

(Ans. 8).

Appellants contend that “[n]one of the references, including Uchimyama et al., expressly teach providing the skin with therapeutic *Pothomorphe umbellata* extract within a skin gel composition including photoprotective activity” (App. Br. 11). Appellants contend that “the therapeutic gel composition of the present application is not merely a matter of common selection and routine optimization which is well within the experience of a person with ordinary skill in the art” (App. Br. 11).

Appellants contend that

according to the Examiner, any antioxidant added to any formulation would produce the effect showed in claim 28. Applicants respectfully disagree with the Examiner. Not all photoprotectors are antioxidants. In most cases, the photoprotector acts as a barrier function and has no antioxidant activity. Also, not all antioxidants have photoprotective activity, and in equal intensity. One reason for this is that for performing the effect demonstrated in the present application, the active ingredient must permeate the skin which was only achieved in the present application

(App. Br. 12). Appellants contend that “it would not be possible to foresee that such gel composition with *Pothomorphe umbellata* extract had photoprotective activity.” (App. Br. 13).

The issue with respect to this rejection is: Does the evidence of record support the Examiner’s conclusion that the claimed invention is obvious over the prior art?

Findings of Fact

15. Uchiyama teaches “[t]o obtain a composition for external use having an extremely wide application due to stability and excellently preventing or improving effects on reduction in biofunction caused by environmental stress and aging, especially reduction in functions of the skin the hair and oral cavity tissue” (Uchiyama abstract).

16. Uchiyama teaches the use of extracts of plants including *Umbellata potomorphe* (see Uchiyama 2 ¶¶ 0007-0008).

17. Uchiyama teaches the “external use constituent of this invention is stable, and since it is excellent in the effectiveness of preventing or improving the fall of the living body function caused by environmental stress and aging . . . its application range is very wide” (Uchiyama 3 ¶ 0016).

18. Barros teaches that “*P. umbellata* roots are the most active part of the plant concerning antioxidant activity . . . 4-Nerolidylcatechol isolated from *P. umbellata* root extract was assayed for its antioxidant activity . . . and compared with α -tocopherol” (Barros 116, col. 1).

19. Barros teaches that the “results indicate a very high antioxidant activity of 4-nerolidylcatechol when compared with that of α -tocopherol in the experimental model employed” (Barros 116, col. 2).

20. Desmarchelier teaches that “[r]oots and leaves of *Pothomorphe umbellata* (L.) Miq. . . . are widely used in the treatment of liver diseases and other inflammatory disorders in tropical South America” (Desmarchelier 561, col. 1).

21. Desmarchelier teaches that “[d]ifferent extracts of these plants have been shown to reduce oxidative stress . . . This activity has been

attributed to the presence of the catechol derivative 4-nerolidylcatechol . . . present in both species” (Desmarchelier 561, col. 1).

Analysis

Uchiyama teaches the use of extracts of *Umbellata potomorphe* to treat aging in skin and other tissues (FF 15-16). Uchiyama teaches that the composition is stable and is for external use (FF 17). Barros and Desmarchelier demonstrate that *Umbellata potomorphe* extracts will comprise 4-nerolidylcatechol (FF 18-21).

Wheeler teaches skin cleansing products with antioxidants, carboxymethylcellulose, where the “preservatives (methylparaben and imidazolidinylurea) were dissolved in the propylene glycol” which resulted in “a clear aqueous gel” (Wheeler, col. 4, ll. 60-67; FF 12). Wheeler teaches the use of 0.08 % methylparaben and 3% propylene glycol in Example 1 (*see* Wheeler, col. 4, ll. 52-56; FF 13).

We agree with the Examiner that it would have been obvious to the ordinary artisan to incorporate the *P. umbellata* root extract taught by Uchiyama, which inherently comprises 4-nerolidylcatechol as evidenced by Barros and Desmarchelier, with the skin gel components taught by Wheeler to obtain a “composition for external use having an extremely wide application due to stability and excellently preventing or improving effects on reduction in biofunction caused by environmental stress and aging” (Uchimiyama abstract; FF 15).

Appellants contend that “[n]one of the references, including Uchimiyama et al., expressly teach providing the skin with therapeutic

Pothomorphe umbellata extract within a skin gel composition including photoprotective activity” (App. Br. 11).

We are not persuaded. For claims 24 and 27, the only functional requirement is for a topical gel, which is taught by Wheeler (FF 10-11). For claim 28, the preamble is drawn to three alternative treatments, one of which is cutaneous aging, and Uchiyama teaches “a composition for external use . . . and excellently preventing or improving effects on reduction in biofunction caused by environmental stress and aging” (Uchiyama abstract; FF 15). Consequently, the prior art renders obvious a gel which satisfies the claim requirements.

Appellants contend that “the therapeutic gel composition of the present application is not merely a matter of common selection and routine optimization which is well within the experience of a person with ordinary skill in the art” (App. Br. 11).

As we discussed regarding the previous rejection, we also conclude that the close, but not overlapping, range of amounts of components disclosed by Wheeler would reasonably be obtained by those in the art seeking to optimize the properties of the composition. *See In re Peterson*, 315 F.3d 1325, 1329 (Fed. Cir. 2003) (“[A] *prima facie* case of obviousness exists when the claimed range and the prior art range do not overlap but are close enough such that one skilled in the art would have expected them to have the same properties.”).

Appellants contend that

according to the Examiner, any antioxidant added to any formulation would produce the effect showed in claim 28. Applicants respectfully disagree with the Examiner. Not all

photoprotectors are antioxidants. In most cases, the photoprotector acts as a barrier function and has no antioxidant activity. Also, not all antioxidants have photoprotective activity, and in equal intensity. One reason for this is that for performing the effect demonstrated in the present application, the active ingredient must permeate the skin which was only achieved in the present application

(App. Br. 12). Appellants contend that “it would not be possible to foresee that such gel composition with *Pothomorphe umbellata* extract had photoprotective activity.” (App. Br. 13).

We are not persuaded. The claims are not so limited. Claim 28 does not require photoprotective activity, but is open to treating cutaneous aging, as taught by Uchiyama (FF 15). “[L]imitations are not to be read into the claims from the specification.” *In re Van Geuns*, 988 F.2d 1181, 1184 (Fed. Cir. 1993) (citing *In re Zletz*, 893 F.2d 319, 321 (Fed. Cir. 1989)).

Conclusion of law

The evidence of record supports the Examiner’s conclusion that the claimed invention is obvious over the prior art.

SUMMARY

In summary, we reverse the rejection claims 24, 27, and 28 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement).

We affirm the rejection of claims 24, 27, and 28 under 35 U.S.C. § 103(a) as obvious over Ropke (2002), Ropke (2000), and Wheeler.

We affirm the rejection of claims 24, 27, and 28 under 35 U.S.C. § 103(a) as obvious over Uchiyama, Barros, Desmarchelier, and Wheeler.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

alw

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